



#5

Case No.: BENDE-008B
Patent Appln.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant's: Theodore V. Benderev)
Serial No.: 09/197,938 → 733455)
Filed: November 23, 1998)
For: System & Method for Securing)
Sutures to Bone & Tissue)

Art Unit: 3731
Examiner: David O. Reip

DECLARATION UNDER 37 C.F.R. §132

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON D C 20231

Dear Sir/Madam:

I, Theodore V. Benderev, M.D., the undersigned, hereby declare that:

1. I am a board certified surgeon specializing in Urology and experienced in a wide variety of surgical procedures, including surgical procedures deploying the use of implantable devices for attaching sutures, grafts, synthetic materials, and soft tissue to bone and/or soft tissue. Attached hereto as Exhibit "A" is my curriculum vitae which correctly identifies my educational background, experience, and the papers that I have offered and/or co-authored that have been published.

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2. Based upon my 16 years of experience practicing surgery, I am familiar with current clinical procedures and practices which incorporate the use of surgical implants for use in attaching sutures, grafts, synthetic materials, and/or soft tissue to bone and/or soft tissue, and have first hand knowledge and experience with respect to preferred clinical methodology in systems utilized in relation to such implant devices and methodology.

3. The surgical staples and methods of deploying the same disclosed in United States Patent No. 5,242,457 to Akopov et al., discloses a plurality of surgical staples that are designed to be stapled into soft tissue such that a suture may be affixed thereto, and more particularly a purse string suture to human tissue. Such surgical staples are typical of those known in the art and require that the same be deployed by the use of a surgical stapler. In this respect, such staples cannot be manually positioned upon the tissue, but rather must be meticulously inserted into the stapler deployment mechanism and accurately stapled at the target site to which the suture is to be attached.


4. Such surgical staples and procedures by which the same are deployed as disclosed in the aforementioned patent to Akopov et al., is often times ill-suited to provide optimal attachment means by which a suture, graft, material and/or soft tissue is secured to a target site within the body, whether such target site comprise bone or soft tissue. For example, in order to utilize the surgical staple requires that the same must be meticulously oriented at the target site. Such procedure requires switching instruments and precisely orienting such deployment stapler so that the staple may be accurately deployed at the desired site. It is well-known that such procedure is time consuming, inefficient and requires great skill. Indeed, to the extent a staple, such as those that Akopov et al. are deployed at the wrong site, such are often irretrievable and frequently must remain in the patient indefinitely. Moreover, the design of such staples is somewhat inefficient insofar as the same do not necessarily remain firmly embedded within the tissue, and can be readily caused to detach therefrom once tension is applied thereto.

5. The devices and methods disclosed in the present application, in contrast, offer tremendous advantages over prior art anchoring systems, and in particular the staples that are the subject of the Akopov et al. reference. Specifically, the devices of the present invention may be advantageously positioned by hand, which allows for greater accuracy and placement of the anchors at the target tissue/bone site, as well as is far more rapid than having to deploy the same via a stapler or other similar type device. Likewise, by virtue of the ability of such device to remain more firmly embedded within the tissue or bone at the target site, particularly when the stress suture is imparted thereto, such devices will, in fact, provide the surgeon with greater confidence that the same will remain firmly embedded at the desired location and will not slip or otherwise disengage from such target site unless selectively caused to do so.

6. Indeed, the fixation devices and methods that are the subject of the present application have revolutionary applicability in certain advance techniques for performing pubovaginal sling surgery, as described in the present application, insofar as the same may be utilized to attach the sling to periosteum or rectus facia. In this regard, there is not hereto for been available any type of anchoring device specifically designed for use in pubovaginal sling surgery that enables the sling to be adequately secured to such target sites (i.e., the rectus fascia or periosteum about the pubic bone) and, but for the novel devices and the methods of the present invention, I am unaware of any type surgical staple, anchor and/or implant that has the ability to be manually deployed at a target site, whether it be bone or soft tissue, that is actually operative to become more firmly embedded within such target site as tension is applied thereto.

7. I hereby declare that all statements made here and are of my own knowledge and are true and that all statements made on information in belief are believed to be true; and further, that the statements were made with the knowledge that willful of all statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: 3-15-01

Signed: 
Theodore Benderev, M.D.



CURRICULUM VITAE

THEODORE VAL BENDEREV, M.D.

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PRESENT POSITION	Private Practice Associate Clinical Professor Division of Urology Department of Surgery University of California, Irvine	TECHNOLOGY CENTER R3700
OFFICE ADDRESSES	2/98 to Present - 4/87 to 2/98 -	The Incontinence and Pelvic Support Institute 26732 Crown Valley Parkway, Suite 327 Mission Viejo, CA 92691 Phone: (949) 364-4400 FAX: (949) 364-2829 Orange County Urology Associates 26732 Crown Valley Parkway, Suite 321 Mission Viejo, CA 92691 Phone: (949) 365-8000
HOME ADDRESS	26975 Magnolia Court Laguna Hills, CA 92653 Phone: (949) 348-9705 FAX: (949) 348-2856	
CERTIFICATION	Diplomate, American Board of Urology Diplomate, National Board of Medical Examiners	
LICENSURE	California G 043662	

THEODORE VAL BENDEREV
PAGE TWO

POSTGRADUATE TRAINING

Intern - Surgery
University of California, San Diego
July, 1979 - June, 1980

Assistant Resident - Surgery
University of California, Irvine
Orange, California
July, 1980 - June, 1981

Resident - Urology
Northwestern University Medical Center
Chicago, Illinois
July, 1981 - June, 1985

EDUCATION	1972 – 1973	Georgetown University Washington, D.C.
	1973 - 1975	Bachelor of Science University of Maryland College Park, Maryland
	1975 - 1979	Doctor of Medicine University of Maryland School of Medicine Baltimore, Maryland

HONORS

A. Bradley-Gaither Memorial Prize for Excellence in Genito-Urinary Surgery

First Prize Clinical Research - "Anchor fixation and other modifications of the endoscopic bladder neck suspension" Western Section American Urological Association Meeting, October, 1992.

Award for Outstanding Achievement - "A new endoscopic bladder neck suspension for the outpatient treatment of stress urinary incontinence" 1993 Video Urology Times

RESEARCH EXPERIENCE

1982 – 1985	Study of Laser Lithotripsy and Dosimetry under Dr. Anthony Schaeffer at Northwestern University Department of Urology.
1986 – 1987	Principal Investigator for Pulse Dye Laser Lithotripter Study for Ureteral Stones. University of California at Irvine Department of Surgery.

THEODORE VAL BENDEREV
PAGE THREE

RESEARCH EXPERIENCE (cont.)

1993	Principal Investigator for Percutaneous Bladder Neck Suspension Study. Mission Hospital Regional Medical Center. Mission Viejo, California.
1995 - 1996	Sub-investigator for Tolterodine Drug Study. The Incontinence Treatment Center. Mission Viejo, California.
1998 - 1999	Principal Investigator for pelvic floor rehabilitation device study. The Incontinence and Pelvic Support Institute. Mission Viejo, California
2000 - 2001	Principal Investigator for tension setting monitor for sling surgery. The Incontinence and Pelvic Support Institute. Mission Viejo, California
2001 – Present	Sub-investigator for urethral bulking agent. The Incontinence and Pelvic Support Institute. Mission Viejo, California
2001- Present	Principal Investigator for suture fixation device for sling surgery. The Incontinence and Pelvic Support Institute. Mission Viejo, California
2001- Present	Sub-investigator for overactive bladder drug study. The Incontinence and Pelvic Support Institute. Mission Viejo, California

PATENTS

Medical instrument for containment and removal of calculi	Pat. 4,611,594
Suture passer	Pat. 5,439,467
Method of advancing a suture through tissue	Pat. 5,544,664
Method of tensioning a suspended tissue mass	Pat. 5,582,188
Bladder neck suspension procedure	Pat. 5,611,515
Method of percutaneously anchoring a suture to a bone	Pat. 5,620,012
Device for supporting and positioning medical equipment	Pat. 5,746,763
Bone anchor implantation device and method	Pat. 5,749,884
Bone anchor implantation device	Pat. 5,766,221
Device & methods for assesment & treatment for urinary & fecal incontinence	Pat. 5,782,745
Surgical Drape	Pat. 5,813,408
Surgical treatment of stress urinary incontinence	Pat. 5,836,314
Method of tensioning a suspended tissue mass	Pat. 5,836,315
Method of securing a bone anchor	Pat. 5,842,478
Bladder neck suspension procedure	Pat. 5,860,425
Electrosurgical instrument and method of use	Pat. 5,919,189
External vibratory exercising device for pelvic muscles	Pat. 6,030,338
Electrosurgical instrument and method of use	Pat. 6,030,383
Surgical Tension/Pressure Monitor	Pat. 6,050,937
Devices and methods for assesment and treatment of urinary & fecal incontinence	Pat. 6,110,099
Systems for securing sutures, grafts and soft tissue to bone and periosteum	Pat. 6,200,330

THEODORE VAL BENDEREV
PAGE FOUR

SOCIETIES American Urologic Association
 Society of University Urologists
 American UroGynecologic Society
 California Medical Association
 Western Section American Urological Society
 American Medical Association
 Orange County Medical Association

COMMITTEES	Surgery Executive Committee (Mission Hospital)	1988 - 1999
	Chief, Division of Urology	
	Member, Scientific Advisory Panel on Urology	1994
	California Medical Association	
	President, Orange County Urological Society	1993
	Vice-President, Orange County Urological Society	1992
	Secretary/Treasurer, Orange County Urologic Society	1991
	Surgery Executive Committee (Samaritan Hospital)	1988 - 1992
	Chief, Division of Urology	
	Chairman, Urology Section,	1987
	American Soc. for Laser Medicine and Surgery	

PRESENTATIONS

1. Inferior vena cava obstruction secondary to adenocarcinoma of the prostate: The role of orchiectomy in treatment. North Central Section American Urologic Association Meeting. Marco Island, Florida. October, 1982.
2. Ultrasonic and electrohydraulic lithotripsy. Clinical Problems in Urology. Chicago, Illinois. June, 1983.
3. The use of the Nd:YAG laser in canine renal surgery. North Central Section American Urologic Association Meeting, Maui, Hawaii. October, 1983.
4. Dosimetry of the Nd:YAG laser on canine renal cortex. Annual American Urologic Association Meeting. New Orleans, Louisiana. May, 1984.
5. Ultrasonic and electrohydraulic lithotripsy. Clinical Problems in Urology. Chicago, Illinois. June, 1984.
6. Evaluation and management of the neurogenic bladder. Neurosciences Conference. University of California at Irvine. October, 1985.
7. Urologic cancers. Biology of Cancer Lecture Series. University of California at Irvine. February 1986.

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PAGE FIVE

PRESENTATIONS

8. Genitourinary trauma. California Medical Association Meeting. Los Angeles, California. March, 1986.
9. Bladder cancer. Radiation Therapy Seminar. Orange Coast College. May, 1986.
10. Laser endoscopy in Urology. American Society for Laser Medicine and Surgery Annual Meeting. Boston, MA., May. 1986.
11. Oral and percutaneous acetylcysteine for urinary tract mucolysis. Western Section American Urologic Association Meeting. Seattle, WA. July, 1986.
12. Partial penectomy with flap penoplasty as a substitute for total penectomy in penile carcinoma. Western Section American Urologic Association Meeting. Seattle, WA. July, 1986.
13. Urinary incontinence in the elderly. Primary Care Grand Rounds. University of California at Irvine. November, 1986.
14. Ureteroscopy - techniques and use of laser lithotripter for ureteral stones. Fourth Annual Reider Laser Center Symposium. Long Beach, CA, January, 1987
15. Fiberoptic laser lithotripsy. Nephrology Grand Rounds. University of California at Irvine. February, 1987.
16. Initial clinical experience with the fiberoptic laser lithotripter. Western Section American Urologic Association Meeting. Kona, Hawaii. February, 1987.
17. Lasers in Urology. Seventh Annual Meeting of the American Society for Laser Medicine and Surgery, San Francisco, CA. April, 1987.
18. Pulsed-Dye Laser Lithotripsy of Ureteral Stones. Seventh Annual Meeting of the American Society for Laser Medicine and Surgery. San Francisco, CA. April, 1987
19. Impotence in the Multiple Sclerosis Patient. Multiple Sclerosis Society Seminar. Mission Viejo, CA. October, 1987.
20. New Treatments in Urology. First Annual Topics in Primary Care. Snowbird, Utah. January, 1989.
21. Advances in the Treatment of Stress Urinary Incontinence. Topics in Primary Care. Steamboat Springs, Colorado. January, 1991.
22. Modern Treatment of Stress Urinary Incontinence. University of California at Irvine Family Practice Refresher Course. Irvine, California. June 11, 1991.

THEODORE VAL BENDEREV
PAGE SIX

23. Advances in the surgical treatment of stress urinary incontinence. Grand Rounds. University of California at Irvine. August, 1991.
24. Modifications in the surgical treatment of stress urinary incontinence. Grayhack Fest. Northwestern University. Chicago, Illinois. September, 1991.
25. Anchor fixation in the shortstay treatment of stress urinary incontinence. International Meeting of the Society for Minimally Invasive Therapy. Boston, Massachusetts. November, 1991.
26. Understanding urinary leakage in the active woman. Annual Meeting of the American Urological Association. Washington, D.C. May, 1992.
27. Anchor fixation and other modifications of the endoscopic bladder neck suspension. Western Section Meeting of the American Urological Association. Maui, Hawaii. October, 1992.
28. Modifications of the endoscopic bladder neck suspension utilizing the Mitek G2 Anchor. Videourology - Fourth World Congress. Monte-Carlo. October, 1992.
29. A new endoscopic bladder neck suspension for the outpatient treatment of stress urinary incontinence. Annual Meeting of the American Urological Association. San Antonio, Texas. May, 1993.
30. Anchor fixation and other modifications of the endoscopic bladder neck suspension. Annual Meeting of the American Urological Association. San Antonio, Texas. May, 1993.
31. The Benderev procedure. Invited speaker. Videourology - Fifth World Congress. Orlando, Florida. June, 1993.
32. Update on a New Outpatient Bladder Neck Suspension System. Annual Meeting of the American Uro-Gynecological Society and the Urodynamic Society. San Antonio, Texas. October, 1993.
33. Mechanical properties of various suture materials used in bladder neck suspension procedures. Accepted for presentation at the Annual Meeting of the American Urological Association. San Francisco, California. May, 1994.
34. Needle suspension procedures: Evolution and review of the literature. Invited presentation. Urogynecology and disorders of the female pelvic floor: 7th annual conference. Mayo Clinic Scottsdale, Arizona. March, 1998.
35. Incontinence Techniques. Invited speaker. Annual Meeting of the New York Section American Urological Association. South Africa. October, 2000.

THEODORE VAL BENDEREV
PAGE SEVEN

PUBLICATIONS

1. Smith AD, Lee WJ, Benderev TV. Percutaneous management of urinary calculi: clinical studies of a new approach. *Internal Medicine for the Specialist*. 4, 1983.
2. Benderev TV, Grayhack JT. Prostate Carcinoma. In: *Current Diagnosis 7*. Edited by RB Conn, Jr. Philadelphia: WB Saunders. P. 1134-1137, 1984.
3. Benderev TV, Schaeffer AJ. Preliminary study of the Nd:YAG laser in canine partial nephrectomy. *Lasers in Surgery and Medicine*. 5: 415, 1985.
4. Benderev TV, Schaeffer AJ. Efficacy and safety of the Nd:YAG laser in canine partial nephrectomy. *Journal of Urology*. 133: 1108, 1985.
5. Benderev TV, Bockrath JM, Uke ET, Grayhack JT. Inferior vena cava obstruction secondary to adenocarcinoma of the prostate: the role of orchiectomy in treatment. *Archives of Internal Medicine*. 146: 598, 1986.
6. Benderev TV. Mucolytic agent to relieve mucinous obstruction of the ureter. *Urology Times*. 11, 1986.
7. Benderev TV, Chmiel JS, Carone FA, Schaeffer AJ. Dosimetric study of Nd:YAG laser damage of the canine renal cortex. *Lasers in Surgery and Medicine*. 7: 363, 1987.
8. Benderev TV. Preservation of penile length in penile cancer and trauma by use of a pedicled flap. *Journal of Urology*. 140: 145, 1988.
9. Benderev TV. Acetylcysteine for urinary tract mucolysis. *Journal of Urology*. 139: 353, 1988.
10. Benderev TV. Laser Lithotripsy: An effective adjunct in ureteral stone removal. *Urology Times*. 16: 24, 1988.
11. Benderev, T.V. Anchor fixation and other modifications in the treatment of stress urinary incontinence. *Urology*. 40: 409, 1992.
12. Benderev, T.V. A new outpatient percutaneous bladder neck suspension. *Video Urology Times*. 6:2, 1993.
13. Benderev, T.V. A modified percutaneous outpatient bladder neck suspension system. *Journal of Urology*. 152: 2316, 1994.

THEODORE VAL BENDEREV
PAGE EIGHT

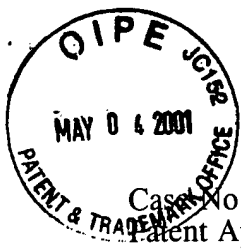
PERSONAL INFORMATION

Date of Birth: February 5, 1954

Place of Birth: New York, New York

Married: Katherine P. Benderev, Pharm. D.
June 16, 1979

Son: Christopher Benderev



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Case No.: BENDE-008B

Patent Appln.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant's:	Theodore V. Benderev)	Art Unit:	3731
Serial No.:	09/197,938)	Examiner:	David O. Reip
Filed:	November 23, 1998)		
For:	System & Method for Securing)		
	Sutures to Bone & Tissue)		

DECLARATION UNDER 37 C.F.R. §132

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON D C 20231

Dear Sir/Madam:

I, Tom D. Thomas, M.D., the undersigned, hereby declare that:

1. I am a board certified surgeon specializing in Orthopedics and experienced in a wide variety of surgical procedures, including surgical procedures deploying the use of implantable devices for attaching sutures, grafts, synthetic materials, and soft tissue to bone and/or

soft tissue. Attached hereto as Exhibit "A" is my curriculum vitae which correctly identifies my educational background, experience, and the papers that I have offered and/or co-authored that have been published.

2. Based upon my 8 years of experience practicing surgery, I am familiar with current clinical procedures and practices which incorporate the use of surgical implants for use in attaching sutures, grafts, synthetic materials, and/or soft tissue to bone and/or soft tissue, and have first hand knowledge and experience with respect to preferred clinical methodology in systems utilized in relation to such implant devices and methodology.

3. The surgical staples and methods of deploying the same disclosed in United States Patent No. 5,242,457 to Akopov et al., discloses a plurality of surgical staples that are designed to be stapled into soft tissue such that a suture may be affixed thereto, and more particularly a purse string suture to human tissue. Such surgical staples are typical of those known in the art and require that the same be deployed by the use of a surgical stapler. In this respect, such staples cannot be manually positioned upon the tissue, but rather must be meticulously inserted into the stapler deployment mechanism and accurately stapled at the target site to which the suture is to be attached.

4. Such surgical staples and procedures by which the same are deployed as disclosed in the aforementioned patent to Akopov et al., is often times ill-suited to provide optimal attachment means by which a suture, graft, material and/or soft tissue is secured to a target site

within the body, whether such target site comprise bone or soft tissue. For example, in order to utilize the surgical staple requires that the same must be meticulously oriented at the target site. Such procedure requires switching instruments and precisely orienting such deployment stapler so that the staple may be accurately deployed at the desired site. It is well-known that such procedure is time consuming, inefficient and requires great skill. Indeed, to the extent a staple, such as those that Akopov et al. are deployed at the wrong site, such are often irretrievable and frequently must remain in the patient indefinitely. Moreover, the design of such staples is somewhat inefficient insofar as the same do not necessarily remain firmly embedded within the tissue, and can be readily caused to detach therefrom once tension is applied thereto.

5. The devices and methods disclosed in the present application, in contrast, offer tremendous advantages over prior art anchoring systems, and in particular the staples that are the subject of the Akopov et al. reference. Specifically, the devices of the present invention may be advantageously positioned by hand, which allows for greater accuracy and placement of the anchors at the target tissue/bone site, as well as is far more rapid than having to deploy the same via a stapler or other similar type device. Likewise, by virtue of the ability of such device to remain more firmly embedded within the tissue or bone at the target site, particularly when the stress suture is imparted thereto, such devices will, in fact, provide the surgeon with greater confidence that the same will remain firmly embedded at the desired location and will not slip or otherwise disengage from such target site unless selectively caused to do so.

6. Indeed, the fixation devices and methods that are the subject of the present application have revolutionary applicability in certain advance techniques for performing pubovaginal sling surgery, as described in the present application, insofar as the same may be utilized to attach the sling to periosteum or rectus facia. In this regard, there is not hereto for been available any type of anchoring device specifically designed for use in pubovaginal sling surgery that enables the sling to be adequately secured to such target sites (i.e., the rectus fascia or periosteum about the pubic bone) and, but for the novel devices and the methods of the present invention, I am unaware of any type surgical staple, anchor and/or implant that has the ability to be manually deployed at a target site, whether it be bone or soft tissue, that is actually operative to become more firmly embedded within such target site as tension is applied thereto.

//

7. I hereby declare that all statements made here and are of my own knowledge and are true and that all statements made on information in belief are believed to be true; and further, that the statements were made with the knowledge that willful of all statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: 4-11-01

Signed: Tam D. Hanna MD



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CURRICULUM VITAE

TOM D. THOMAS, M.D.

ORTHOPEDIC SURGEON

**COMMUNITY ORTHOPEDIC MEDICAL GROUP
26401 CROWN VALLEY PARKWAY, SUITE 101
MISSION VIEJO, CALIFORNIA 92691**

JUNE 2000



**TOM D. THOMAS, M.D.
CURRICULUM VITAE**

-2-

PERSONAL DATA

Date of Birth: November 7, 1954
Place of Birth: Corona, California
Married with two children
Spouse Name: Barbara

EDUCATION

1977	University of California at Los Angeles Los Angeles, California B.A. Biology
1987	University of California at Los Angeles School of Medicine M.D., June 1987

POST DOCTORAL TRAINING

1987-1988	UCLA Medical Center Department of Surgery Los Angeles, California General Surgery Internship
1988-1991	UCLA Medical Center Division of Orthopedic Surgery Los Angeles, California Orthopedic Surgery Resident
1991-1992	UCLA Medical Center Division of Orthopedic Surgery Los Angeles, California Orthopedic Surgery Chief Resident
1992-1993	The Sports Clinic Laguna Hills, California Sports Medicine Fellowship

TOM D. THOMAS, M.D.
CURRICULUM VITAE

-3-

HONORS AND AWARDS

1986	Honors Program - Department of Surgery UCLA School of Medicine
1987	Alpha Omega Alpha UCLA School of Medicine

LICENSURE AND CERTIFICATION

Diplomate of the American Board of Orthopaedic Surgery
Board Certified, 1995

Diplomate of the National Board of Medical Examiners
351036, 1988

California State Medical License
G063599

DEA Registration
BT1694492

SOCIETY MEMBERSHIPS

American Academy of Orthopaedic Surgeons: Fellow

Arthroscopy Association of North America: Member

American College of Sports Medicine: Member

Orange County Medical Association

California Medical Association

TOM D. THOMAS, M.D.
CURRICULUM VITAE

4

HOSPITAL STAFF POSITIONS

1996-1997 Chairman, Department of Orthopedic Surgery, Mission Hospital
Regional Medical Center, Mission Viejo, California

PUBLICATIONS AND PRESENTATIONS

Davlin, L., Johnson, E., Thomas, T., Lian, G.:
Open Versus Closed Nailing of Femur Fractures in the Polytrauma Patient.
Contemporary Orthopaedics, May 1991; Presented at the A.A.O.S., February
1990, New Orleans, Louisiana

Thomas, Tom D.:
Arthroscopic Shoulder Surgery Hands-On Cadaver Surgical Workshop;
Arthroscopic A/C Joint Resection; Presented March 19, 1993, Laguna Hills,
California

EMPLOYMENT HISTORY

1993 – Present
Orthopedic Surgeon
Community Orthopedic Medical Group
Mission Viejo, California 92691

FACULTY POSITIONS

Assistant Clinical Instructor, University of California at Irvine

Shoulder Arthroscopy Instructor, Shoulder Arthroscopy 1999 Update,
June 23-26, La Jolla California

Associate Master Instructor, "The Masters Experience", Advanced Shoulder Arthroscopy.
Orthopaedic Learning Center, March 19-21, 1999, Rosemont, Illinois.

Associate Master Instructor, "The Masters Experience", Advanced Shoulder Arthroscopy.
Orthopaedic Learning Center, August 14-16, 1998, Rosemont, Illinois.

TOM D. THOMAS, M.D.
CURRICULUM VITAE

-5-

FACULTY POSITIONS CONTINUED

Shoulder Arthroscopy Instructor, Shoulder Arthroscopy 1998 Update,
June 24-27, La Jolla California

Associate Master Instructor, "The Masters Experience", Shoulder Arthroscopy,
Orthopaedic Learning Center, May 29-31, 1998, Rosemont, Illinois.

Shoulder Arthroscopy Instructor, Arthroscopy Association of North
America Fall Course, November 8-9, 1997, Nashville, Tennessee

Shoulder Arthroscopy Instructor, Shoulder Arthroscopy 1997 Update,
June 18-21, La Jolla, California.

Associate Master Instructor, "The Masters Experience", Shoulder Arthroscopy,
Orthopaedic Learning Center, March 21-23, 1997, Rosemont, Illinois.

Shoulder Arthroscopy Instructor, Shoulder Arthroscopy 1996 Update,
June 26-29, La Jolla, California.

Associate Master Instructor, "The Masters Experience", Shoulder Arthroscopy,
Orthopaedic Learning Center, June 8-9, 1996, Rosemont, Illinois.

Shoulder Arthroscopy Instructor, Shoulder Arthroscopy 1995 Update,
June 14-17, La Jolla, California.

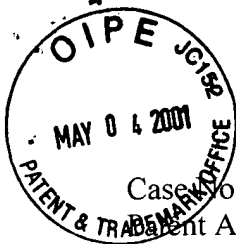
Shoulder Arthroscopy Instructor, Shoulder Arthroscopy 1994 Update,
June 15-18, La Jolla, California.

Shoulder Arthroscopy Instructor, Arthroscopy Association of North
America Fall Course, October 6-9, 1993, Albuquerque, New Mexico

Shoulder Arthroscopy Instructor, Shoulder Arthroscopy 1993 Update,
June 16-19, La Jolla, California.

Shoulder Arthroscopy Instructor, Hands-On Cadaver Surgical Workshop,
March 19-20, 1993, Laguna Hills, California.

Knee Arthroscopy Instructor, Arthroscopy Association of North
America Fall Course, November 19-22, 1992, Monterey, California.



#5

Case No.: BENDE-008B
Patent Appln.
Certificate of Mailing:

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington D.C. 20231.
Michelle Schroeder

(Signature)

(Date)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant's:	Theodore V. Benderev)	
)	Art Unit: 3731
Serial No.:	09/197,938)	
)	Examiner: David O. Reip
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For:	System & Method for Securing)	
	Sutures to Bone & Tissue)	
)	

DECLARATION UNDER 37 C.F.R. §132

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON D C 20231

Dear Sir/Madam:

I, Stephen DeSantis, M.D., the undersigned, hereby declare that:

1. I am a board certified surgeon specializing in General Surgery and experienced in a wide variety of surgical procedures, including surgical procedures deploying the use of implantable devices for attaching sutures, grafts, synthetic materials, and soft tissue to

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bone and/or soft tissue. Attached hereto as Exhibit "A" is my curriculum vitae which correctly identifies my educational background, experience, and the papers that I have offered and/or co-authored that have been published.

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2. Based upon my 18 years of experience practicing surgery, I am familiar with current clinical procedures and practices which incorporate the use of surgical implants for use in attaching sutures, grafts, synthetic materials, and/or soft tissue to bone and/or soft tissue, and have first hand knowledge and experience with respect to preferred clinical methodology in systems utilized in relation to such implant devices and methodology.

3. The surgical staple and methods of deploying the same disclosed in United States Patent No. 5,242,457 to Akopov et al., discloses a plurality of surgical staples that are designed to be stapled into soft tissue such that a suture may be affixed thereto, and more particularly a purse string suture to human tissue. Such surgical staples are typical of those known in the art and require that the same be deployed by the use of a surgical stapler. In this respect, such staples cannot be manually positioned upon the tissue, but rather must be meticulously inserted into the stapler deployment mechanism and accurately stapled at the target site to which the suture is to be attached.

4. Such surgical staples and procedures by which the same are deployed as disclosed in the aforementioned patent to Akopov et al., is often times ill-suited to provide optimal attachment means by which a suture, graft, material and/or soft tissue is secured to a target site

within the body, whether such target site comprise bone or soft tissue. For example, in order to utilize the surgical staple requires that the same must be meticulously oriented at the target site. Such procedure requires switching instruments and precisely orienting such deployment stapler so that the staple may be accurately deployed at the desired site. It is well-known that such procedure is time consuming, inefficient and requires great skill. Indeed, to the extent a staple, such as those that Akopov et al. are deployed at the wrong site, such are often irretrievable and frequently must remain in the patient indefinitely. Moreover, the design of such staples is somewhat inefficient insofar as the same do not necessarily remain firmly embedded within the tissue, and can be readily caused to detach therefrom once tension is applied thereto.

5. The devices and methods disclosed in the present application, in contrast, offer tremendous advantages over prior art anchoring systems, and in particular the staples that are the subject of the Akopov et al. reference. Specifically, the devices of the present invention may be advantageously positioned by hand, which allows for greater accuracy and placement of the anchors at the target tissue/bone site, as well as is far more rapid than having to deploy the same via a stapler or other similar type device. Likewise, by virtue of the ability of such device to remain more firmly embedded within the tissue or bone at the target site, particularly when the stress suture is imparted thereto, such devices will, in fact, provide the surgeon with greater confidence that the same will remain firmly embedded at the desired location and will not slip or otherwise disengage from such target site unless selectively caused to do so.

6. Indeed, the fixation devices and methods that are the subject of the present application have revolutionary applicability in certain advance techniques for performing pubovaginal sling surgery, as described in the present application, insofar as the same may be utilized to attach the sling to periosteum or rectus facia. In this regard, there is not hereto for been available any type of anchoring device specifically designed for use in pubovaginal sling surgery that enables the sling to be adequately secured to such target sites (i.e., the rectus fascia or periosteum about the pubic bone) and, but for the novel devices and the methods of the present invention, I am unaware of any type surgical staple, anchor and/or implant that has the ability to be manually deployed at a target site, whether it be bone or soft tissue, that is actually operative to become more firmly embedded within such target site as tension is applied thereto.

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7. I hereby declare that all statements made here and are of my own knowledge and are true and that all statements made on information in belief are believed to be true; and further, that the statements were made with the knowledge that willful of all statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: _____

4/3/01

Signed: _____

Stephen DeSantis, M.D.

CURRICULUM VITAE
STEPHEN A. DESANTIS, M.D.

PERSONAL INFORMATION:

Birth Date: March 31, 1950
Birth Place: Los Angeles, CA
Spouse: Maribeth
Children: Elise, Nicole, Stephanie
Home Address: 23802 Inverness
Laguna Niguel, Ca 92677.
Business Address: 26732 Crown Valley Pkwy, #351
Mission Viejo, Ca 92691
(714)364-1007
(714)364-0317fax
Social Security Number: 551-66-1228

EDUCATION:

1979-1983 Residency, Harbor/UCLA Medical
Center, Torrance, California
General Surgery
1978-1979 Internship, Harbor/UCLA Medical
Center, Torrance CA
1978 UCLA School of Medicine, Los
Angeles, CA M.D.
1974 University of California,
Los Angeles, CA M.A. Biology
1973 University of California
B.A. Zoology

HONORS:

Cum Laude- University of
California, 1973
Dean's List- University of
California, 1973

RESEARCH:

1973

Research Assistant, Los Angeles
County Heart Laboratory, UCLA
School of Medicine, Center
for the Health Sciences

LICENSURE:

California- G40996, 1979

SOCIETIES:

American Medical Association
California Medical Association
Orange County Medical Assoc.

FACULTY APPOINTMENTS:

Professional Staff Association
Department of Surgery, Harbor-
UCLA Medical Center

BOARD CERTIFICATION:

American Board of General
Surgery, June 1, 1984 #29703
Recertification 10/22/93
Fellow of American College of
Surgeons 1986

PROFESSION BACKGROUND:

Chief of Surgery, Mission Hosp.
Regional Medical Center